

BRAND NAME JUSTIFICATION AND APPROVAL

Limited Sources Justification and Approval

DSS/PLASTIC SURGERY CLINIC

1. Organization/Line Office

2. Description of Action being approved:

Purchase request is for reconstructive tissue matrix for surgeries for breast cancer patients.

3. Description of Product, Supplies or Services required to meet the Agency's needs:

The Plastic Surgery Clinic is in need of a product that is used for breast cancer patients for reconstructive surgeries. The product must be:

1. 7.3cm x 14.7cm, Contoured, LifeCell Alloderm Tissue Matrix, Product Code: CS1520;
2. 9.6cm x 19.3cm, Contoured, LifeCell Alloderm Tissue Matrix, Product Code: CM1520.

4. An identification of the statutory authority permitting other than full and open competition (Requesting Office completes with assistance of Contract Specialist)

The Statutory Authority for this action is 11.105(a)(1). The particular brand name, product, or feature is essential to the Government's requirements, and market research indicates other companies' similar products, or products lacking the particular feature, do not meet, or cannot be modified to meet, the agency's needs.

5. Identification of the Justification Rationale:

LifeCell is the only known company that can meet the requested required product is used to speed up the revascularization process and allows tissue regenerating. This tissue matrix creates an interface between the breast implant and the surgical flap/soft tissue used to reconstruct the breast mold. Alloderm has shown a decreased in infection rate by 3%. The unique flexibility and composition of the tissue allows our surgeons additional handling of the tissue to work with after the muscle in the surrounding areas has been damaged during the mastectomy or radiation therapy.

In addition, our providers are trained in the use of the Alloderm matrix of no further training need. Other products would inquire in additional cost for all staff members to be trained including the Operating Room technicians and nurses.

6. Best value Determination

Price is \$36,392.00 for the requested tissue matrix.

7. Market Research conducted:

The unique shape and style of the reconstructive tissue allows our surgeons to work with implant and the breast tissue in the surrounding areas has been damaged during the mastectomy or radiation therapy to recreate breast for breast cancer survivors.

8. Statement of actions, if any to remove barriers to competition in the future:

The product may come from any company as long as they are made by LifeCell and Alloderm products.

9. Any other facts supporting justification:

As the technical or requirement personnel, I certify that the evidence of the supporting data that forms of this justification is complete and accurate.


Technical Requirements Personnel

Mr. Chomel, Katherine
USN, AD

Printed Name

19 JAN 17
Date


Contracting Officer

ARNOLD B. REYES
Contracting Officer

JAN 24 2017
Date